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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,505	02/08/2002	Ingrid Henriksen	NIDN-10439	8899

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AMERSHAM HEALTH
IP DEPARTMENT
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EXAMINER	
SHARAREH, SHAHNAM J	

ART UNIT	PAPER NUMBER
1617	10

DATE MAILED: 09/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/071,505	HENRIKSEN ET AL.	
	Examiner	Art Unit	
	Shahnam Sharareh	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *2/8/2002, 7/8/2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *8,9 and 13-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 10-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *7.5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Preliminary Amendment filed on February 08, 2002 has been entered. Claims 1-17 are pending.

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1-12 in Paper No. 9 is acknowledged. Applicant has also elected the species of gas containing contrast agent wherein the gas is present as albumin-stabilized microbubbles. Claim 13-17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Claims 8-9 are also withdrawn from further consideration as being drawn to the nonelected species. Election was made **without** traverse in Paper No. 9.

A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01. Claims 1-7, 10-12 read on the elected species.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Vaughn US Patent 5,242,392.

The instant claim is directed to methods of administering a dispersion to a subject by continuous infusion comprising delivering the dispersion from an upper or lower extremity of an essentially vertically positioned delivery vessel and thereafter admixing said dispersion with a flushing medium prior to administration to the subject.

Vaughn discloses an intravenous piggyback flush apparatus that are suspended on a vertical delivery rack allowing administration of a medication into a patient by the force of gravity in a controlled fashion. (see figure 1, item 52, 53 and 34; col 6, lines 54-64). Vaugh later elaborates on the method of using such apparatus whereby a flush solution such as normal saline is delivered from item 52 (the primary flush solution vessel) into the tubing 24. (see col 5, line31-33; col 7, lines 50-col 8, lines 20). Item 34 (the medicine vessel) contains about 50-150 cc of a medicine in solution or suspension, such as an antibiotic formulation in normal saline. (col 6, lines 15-29). Vaughn finally teaches that both the medicine in the form of a suspension from item 34 and the flushing solution from item 52 are mixed in the tubing 24 prior to being administred to the patient. (col 7, line 19-line 35). Examiner views the instant term "dispersion" to encompass the prior art language "suspension." Accordingly, Vaughn anticipates all limitations of the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vaughn in view of Remington, The Science and Practice of Pharmacy 19th edition, pages 1552-1554, (Remington).

Vaughn's teachings are described above. Vaughn delivers its medication through a rubber diaphragm (port) into the primary fluid via a needle. (see figure 1, items 34, 48, 50; col 6, lines 30-34). Vaughn uses an IV piggyback bag as the delivery vessel. Vaughn does not employ a syringe with a driver as the delivery vessel.

Remington teaches that syringes or piggyback bags essentially achieve the same function as the delivery vessel. (See 4th para at page 1552, and figure 6, 7, pages 1552-1554). Remington specifically states that the drug to be administered is injected into the gum-rubber injection port of the volume control unit to further be diluted with the primary fluid or separate fluid reservoir. The gum-rubber port of Remington provides the same function as Vaughn's rubber diaphragm, item 48. The syringe plunger of Remington meets the limitation of the instant syringe driver because it can be manually or mechanically controlled to adjust the rate of drug administration. Remington further provides for mechanical infusion devices that propel a syringe into the IV tubing by mechanical means. (See page 1554). Thus, for the purposes of intravenous drug delivery, syringes and piggyback bags are viewed to be art equivalent. Remington does not explicitly teach administration of dispersions.

Nevertheless, it would have been obvious to one of ordinary skill in the art at the time of invention to modify Vaughn's method by using a syringe instead of a biggyback bag, because as taught by Remington, the ordinary skill in the art would have had a reasonable expectation of success in effectively delivering a drug of choice when substituting a syringe in place of a biggyback bag to administer a drug of choice into the flushing solution.

4. Claims 1-7, 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vaughn in view of Remington as applied to claims 1-3 above, and further in view of Unger WO 97/48337.

The teachings of Vaughn and Remington are discussed above. The modified teachings of Vaughn meets the limitations of claims 4-7, 10-12 except for specific delivery of gas-containing dispersions comprising albumin stabilized gaseous microbubbles.

Unger teaches delivery of gaseous dispersions comprising stabilized microbubbles by a syringe into a flushing medium containing tubing (see abstract, page 98, lines 1-6; figures 1-2). Unger gaseous suspension comprises suitable perfluorinated hydrocarbon gas such as perfluorobutane, and albumin stabilized microbubbles. (see page 24, line 30-32; page 32, line 29-page 33, line 3; page 34, line7; page 52, line25-page 53, line 20). Unger uses saline as the flushing medium. (see page 73, lines 18-21). Unger's syringe is positioned for upward delivery of his contrast agent (see figure 2). Unger does not explicitly teach the admixing of his contrast agents with the primary IV flush solution prior to patient administration.

However, it would have been obvious to one of ordinary skill in the art at the time of invention to further modify Vaughn's modified method such that instead of Vaughn's suspension, the gaseous dispersions of Unger are delivered into primary flushing line of Vaughn via a syringe driver.

One of ordinary skill in the art would have been motivated to do such modifications because as suggested by Vaughn, employing his method would allow the

entire contrast agent to be administered. Further, as suggested by Unger, using a flushing solution with a contrast agent reduces diagnostic artifacts. Therefore, claims 1-7, 10-12 are prima facia obvious in view of the cited references.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 703-308-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

Shahnam Sharareh, PharmD
Patent Examiner, AU 1617

ss
9/20/03